



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,356	09/11/2003	Duran Yetkinler	SKEL-012	6769

24353 7590 03/09/2006

BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVENUE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER

RAMANA, ANURADHA

ART UNIT PAPER NUMBER

3733

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/661,356	YETKINLER ET AL.	
	Examiner	Art Unit	
	Anu Ramana	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-11 and 31-45 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-11 and 31-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/11/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 7, 2006 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 7-9, 11, 31-33, 36-38, 40-41 and 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Constantz et al. (US 6,149,655).

Constantz et al. disclose a method of introducing calcium phosphate cement for orthopedic applications utilizing a cement delivery means such as a needle wherein the needle is vibrated to enhance perfusion of cement (col. 25, lines 38-59, col. 27, lines 11-57, col. 28, lines 49-67 and col. 29, lines 1-67).

Constantz et al. clearly disclose that vibration can be utilized instead of application of pressure to enhance cement infiltration or promote efficient infiltration (col. 27, lines 31-57). Thus, when vibration is stopped, infiltration would also be "simultaneously stopped" since the driving force for cement delivery would be removed.

Regarding claim 31, Constantz et al. disclose removal of marrow matter prior to introduction of calcium phosphate (col. 26, lines 43-48).

Art Unit: 3733

Regarding claims 44-45, since vibration is being used instead of application of pressure, the applied pressure will be atmospheric or near atmospheric (approximately 14 psi).

Claim Rejections - 35 USC § 102/103

Claims 10 and 42 are rejected under 35 U.S.C. 102(b) as anticipated by Constantz et al. (US 6,149,655) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Constantz et al. (US 6,149,655).

Although Constantz et al. do not make an explicit reference to a vibratory element attached to the cement delivery means or needle such an element would be inherently necessary in order to vibrate the cement delivery needle.

One of ordinary skill in the art would have found it obvious to provide a vibratory element attached to the needle in order to vibrate the needle. To support this position, the Examiner directs Applicants' attention to Sproul (US 6,832,988) who discloses an ultrasonic pulse generator or "vibratory element" 92 attached to an ultrasonic probe 91 in order to vibrate the probe (Fig. 7 and col. 7, lines 15-47).

The method steps of claims 10 and 42 are rendered obvious by the above discussion.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz et al. (US 6,149,655) in view of Sproul (US 6,832,988).

Constantz et al. disclose all elements of the claimed invention except for the step of aspirating marrow from cancellous bone.

Sproul teaches maceration and liquefaction of diseased tissue followed by aspiration during vertebroplasty (col. 1, lines 29-38 and col. 7, lines 15-47).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized aspiration, as taught by Sproul, for removing diseased tissue during according to the method of the combination of Constantz et al. and Sproul.

Claims 34, 35 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz et al. (US 6,149,655) in view of Seki (US 4,961,817).

Constantz et al. discloses all elements of the claimed invention except for a pneumatic vibratory element.

Seki et al. teach a pneumatic vibrator 3B for vibrating a needle-like member 3A (Figure 7 and col. 5, lines 37-47).

It would have been obvious to one of ordinary skill in the art to utilize a pneumatic vibrator or "vibratory element," as taught by Seki, for the purpose of vibrating the needle of Constantz et al., since it was known in the art to utilize a pneumatic vibrator to vibrate a needle-like member.

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz et al. (US 6,149,655).

Constantz et al. disclose that the amount of flowable calcium phosphate cement utilized depends on the nature of the vertebral body being treated (col. 27, lines 2-9).

Constantz et al. disclose all elements of the claimed invention except for the amount of cement being about 4 to 10 cubic centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized 4 to 10 cubic centimeters of cement, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

The Applicant did not present any arguments in the response filed on February 7, 2006. Applicant's arguments submitted under "REMARKS" in the response filed on January 9, 2006 were addressed in the Advisory Action mailed on January 17, 2006. Regarding the limitation "stops simultaneously with cessation of vibration," it is noted that if vibration is used as the driving force instead of pressure for efficient cement infiltration, stopping vibration would remove the driving force and thereby simultaneously stop infiltration.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 3733

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

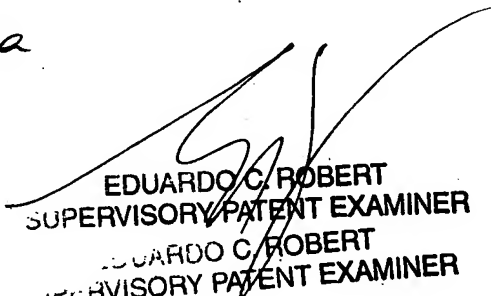
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR

March 5, 2006

Anu Ramana


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER
EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER